

**EPA Registration Number 89966-4**

# PROCESSING REQUEST

**Reg # 89966-4**

**Decision 510433**

**Description: Registration Pyraclostrobin Technical**

**Electronic Label & Letter**  
(see PPLS):

**OR**

**Non Electronic**  
**Label & Letter**  
(Scanning required):

☐ **Dated:**

☐ **Dated:**

\*\*\*Only one label type should be selected\*\*\*

**Other Materials Sent (see jacket):**

☒ **New CSF(s) dated 10/09/2015** *Basic + Alternate*

☐ **Other:**

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

**Reviewer: Craig Reeves**

**Division: RD/FB**

**Phone: 703 347-0486**

**Date: 08/22/2016**



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Registration Division (7505P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

89966-4

Date of Issuance:

8/18/16

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Pyraclostrobin Technical

Name and Address of Registrant (include ZIP Code):

Ann Tillman  
Agent for Greenfields Marketing, Ltd  
c/o Pyxis Regulatory Consulting, Inc.  
4110 136th St. NW  
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Tony Kish, Product Manager 22  
Fungicide Branch, Registration Division (7505P)

Date:

8/18/16

2. Be aware that this registration is subject to satisfying the proposed data requirements identified in the DCI listed in the first website below. For more information on these proposed data requirements, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division in the second website below:

<http://www.regulations.gov/document?D=EPA-HQ-OPP-2014-0051-0019>

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

3. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 89966-4"
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 10/09/2015
- Alternate CSF #1 dated 10/09/2015

Enclosure: Stamped Label

**ACCEPTED**

08/18/2016

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 89966-4

**PYRACLOSTROBIN TECHNICAL**  
FOR USE IN FORMULATING FUNGICIDES ONLY

**ACTIVE INGREDIENT:**

Pyraclostrobin: methyl [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]-  
methoxycarbamate.....99.0%  
**OTHER INGREDIENTS**.....1.0%  
**TOTAL**.....100.0%

**KEEP OUT OF REACH OF CHILDREN****CAUTION – PRECAUCIÓN**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand the label, find someone to explain it to you in detail.)

**FIRST AID**

If on skin:	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15 -20 minutes.</li><li>• Call a Poison Control Center or doctor for treatment advice.</li></ul>
If in eyes:	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15 -20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li><li>• Call a Poison Control Center or doctor for treatment advice.</li></ul>
If swallowed:	<ul style="list-style-type: none"><li>• Call a poison control center or doctor immediately for treatment advice.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• <b>Do not</b> induce vomiting unless told to do so by the poison control center or doctor.</li><li>• <b>Do not</b> give anything by mouth to an unconscious person.</li></ul>
If inhaled:	<ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li><li>• Call a poison control center or doctor for further treatment advice.</li></ul>

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

**HOTLINE NUMBER**

For non-emergency information concerning this product call the National Pesticides Information Center (NPIC) at 1-800-858-7378 Monday through Friday from 8:00 am to 12:00 pm Pacific Time. For emergency information concerning this product call your poison control center at 1-800-222-1222 seven days a week, 24-hours a day.

See additional precautionary statements and directions for use on label.

EPA Reg. No. 89966-

EPA Est. No.

Manufactured for:  
Greenfields Marketing, Ltd.  
P.O. Box 115887, Dubai  
United Arab Emirates

Net Weight: lbs.

**PRECAUTIONARY STATEMENTS  
HAZARD TO HUMANS AND DOMESTIC ANIMALS  
CAUTION**

Harmful if absorbed through skin. Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish and aquatic invertebrates. **Do not** discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutants Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. **Do not** discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency. Notify state and/or Federal authorities immediately if you observe any adverse environmental effects due to use of this product.

**PHYSICAL AND CHEMICAL HAZARDS**

Do not mix or allow coming in contact with oxidizing agent. Hazardous chemical reaction may occur.

**DIRECTIONS FOR USE**

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.**

This product may only be used to formulate fungicide end-use products with the following uses:

(1) foliar use in: alfalfa; Globe artichoke; barley; Belgium endive; brassica head and stem; brassica leafy vegetables; bulb vegetables; bushberries; caneberries; citrus; corn; cotton; cucurbit vegetables; dill seed; dried shelled peas and beans; edible podded legume vegetables; fruiting vegetables; grass grown for seed; herbs; hops; leafy vegetables; leaves of root and tuber vegetables; low growing berries; mint; oats; oilseeds; peanuts; persimmon; pistachio; pomefruit; root vegetables; rye; small fruit, vine climbing (except fuzzy kiwifruit); soybeans; sorghum; succulent shelled peas and beans; sugar beets; sugarcane; stone fruits; strawberries; tree nuts; tuberous and corm vegetables; wheat; triticale; turf and ornamental uses.

(2) seed treatment use in: alfalfa; barley; brassica leafy vegetables; bulb vegetables; corn; cotton; cucurbit vegetables; dried shelled peas and beans; edible podded legume vegetables; fruiting vegetables; leafy vegetables; leaves of root and tuber vegetables; oats; peanut; root vegetables; rye; sorghum; soybean; succulent shelled peas and beans; sugar beet; sunflower; tuberous and corm vegetables; wheat; triticale;

(3) uses for which US EPA has accepted the required data and/or citations of data that the formulator has submitted in the support of registration;

(4) uses for experimental purposes that are in compliance with U.S. EPA requirements.

Each formulator is responsible for obtaining EPA registration for their own end use products.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**STORAGE:** Store in original container in a cool, dry, well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up, and collected and properly disposed.

**PESTICIDE DISPOSAL:** Wastes resulting from using this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be disposed of according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

**CONTAINER HANDLING: DRUM WITH INNER LINER: NONREFILLABLE CONTAINER:** Do not reuse or refill this container. **INNER LINER:** Completely empty removable liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then dispose of empty liner in a sanitary landfill or by incineration or, if allowed by state and local authorities by burning. If burned, stay out of smoke. **DRUM:** Offer for recycling if available or dispose of drum in a sanitary landfill or by incineration or, if allowed by state and local authorities by burning. If burned, stay out of smoke. If drum is contaminated and cannot be reused, dispose of in the same manner required for its liner.

## WARRANTY STATEMENT

**IMPORTANT NOTICE** -Seller warrants that this product conforms to the chemical description and is reasonably fit for purposes stated on the label when used in accordance with the directions and instructions under normal conditions of use. To the extent consistent with applicable law, neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.

[EPA approval date]

**Study Information For  
Product Registration - Section 3  
89966-U**

<b>MRID</b>	<b>Citation</b>	<b>Receipt Date</b>
49750300	Greenfields Marketing, Ltd. (2015) Submission of Product Chemistry Data in Support of the Registration of Pyraclostrobin Technical. Transmittal of 6 Studies.	22-Oct-2015
✓ 49750301	Tillman, A. (2015) Pyraclostrobin Technical: Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits and Enforcement Analytical Method. Project Number: GM/201501. Unpublished study prepared by Greenfields Marketing, Ltd. 195p.	22-Oct-2015
✓ 49750302	Skopec, J. (2015) Preliminary Analyses of Five Representative Production Batches of Pyraclostrobin Technical Grade Active Ingredient (TGAI) to Determine Percent Pyraclostrobin and to Quantify its Associated Impurities. Project Number: WW/051. Unpublished study prepared by AgriFor Scientific Pty Ltd. 286p.	22-Oct-2015
✓ 49750303	Silva, S. (2015) Pyraclostrobin Analytical Profile Study. Project Number: AI/209/14. Study prepared by SAPEC Agro, S.A. 100p.	22-Oct-2015
✓ 49750304	Roehri, C. (2015) Determination of the DMS Relevant Impurity Content in 5 Batches of Pyraclostrobin Technical. Project Number: B5048. Study prepared by Andiaq. 39p.	22-Oct-2015
✓ 49750305	Leopard, B. (2015) Physical and Chemical Characteristics of Pyraclostrobin Technical. Project Number: ARC/EX/1674/013/P/1. Unpublished study prepared by Analytical & Regulatory Chemistry, Inc. 48p.	22-Oct-2015
✓ 49750306	Tillman, A. (2015) Pyraclostrobin Technical Physical and Chemical Properties and Waiver Requests. Project Number: SM/201502. Study prepared by Greenfields Marketing, Ltd. 14p.	22-Oct-2015
Total Rows: 7		



## Reeves, Craig

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**From:** Ann Tillman <Ann@PyxisRC.com>  
**Sent:** Monday, August 08, 2016 2:08 PM  
**To:** Reeves, Craig  
**Subject:** RE: 89966-U: Pyraclostrobin Technical: conference call

Craig,

Yes, Pyxis Regulatory Consulting, Inc. is acting as agent for Greenfields Marketing Ltd. for Pyraclostrobin Technical per the letter of authorization.

Ann

---

**From:** Reeves, Craig [mailto:Reeves.Craig@epa.gov]  
**Sent:** August 08, 2016 11:08 AM  
**To:** Ann Tillman <Ann@PyxisRC.com>  
**Subject:** 89966-U: Pyraclostrobin Technical: conference call

Ann:

Could you confirm that Pyxis Regulatory Consulting, Inc., at this time, is only representing Greenfields Marketing Ltd regarding Pyraclostrobin Technical applications and actions, as stated in the letter dated October 20, 2015

Thanks – Craig

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**From:** Ann Tillman [mailto:Ann@PyxisRC.com]  
**Sent:** Sunday, August 07, 2016 10:49 AM  
**To:** Reeves, Craig <Reeves.Craig@epa.gov>  
**Cc:** Kish, Tony <Kish.Tony@epa.gov>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical: conference call

Craig,

The revised matrices and updated Certification are attached.

Ann

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**From:** Reeves, Craig [mailto:Reeves.Craig@epa.gov]  
**Sent:** August 05, 2016 9:39 AM  
**To:** Ann Tillman <Ann@PyxisRC.com>  
**Subject:** 89966-U: Pyraclostrobin Technical: conference call

Ann:

Since a DCI Pyraclostrobin was sent out October 2015 there are some conditions (mostly Data Matrix) to be discussed.

Would you be available for a conference call today? If so please provide me with 2 options for today, the call should take about 20 minutes.

Thanks – Craig

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**From:** Ann Tillman [mailto:Ann@PyxisRC.com]  
**Sent:** Thursday, August 04, 2016 3:07 PM  
**To:** Reeves, Craig <Reeves.Craig@epa.gov>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical

Craig,

Changes were made. See attachment.

Ann

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**From:** Reeves, Craig [mailto:Reeves.Craig@epa.gov]  
**Sent:** August 04, 2016 11:25 AM  
**To:** Ann Tillman <Ann@PyxisRC.com>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical

Ann:

Please add the following to 89966-U label, page 3, "STORAGE" section:

"Store in original container in a cool, dry, well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up, and collected and properly disposed." The preceding section is from 7969-185.

Please send me the revised label as soon as possible.

Regards – Craig

---

**From:** Ann Tillman [mailto:Ann@PyxisRC.com]  
**Sent:** Thursday, August 04, 2016 8:29 AM  
**To:** Reeves, Craig <Reeves.Craig@epa.gov>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical

Craig,

I made the changes to indicate NPIC for non-emergency calls and the national poison control center for emergency calls. Let me know if that text is acceptable.

Ann

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**From:** Reeves, Craig [mailto:Reeves.Craig@epa.gov]  
**Sent:** August 04, 2016 8:14 AM  
**To:** Ann Tillman <Ann@PyxisRC.com>  
**Subject:** 89966-U: Pyraclostrobin Technical

Ann:

When I looked at NPIC (National Pesticides Information Center: 800-858-1378) this morning, I see that they are "open from 8:00am to 12:00pm Pacific (Standard) time Monday – Friday". Please revise your NPIC information on Page 1 of the label. The information at this website is not for emergencies but is informational.

Please send me revised labels as soon as possible.

Thanks – Craig

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**From:** Ann Tillman [mailto:Ann@PyxisRC.com]

**Sent:** Tuesday, August 02, 2016 8:31 AM

**To:** Reeves, Craig <Reeves.Craig@epa.gov>

**Subject:** RE: 89966-U: Pyraclostrobin Technical

Craig,

Thanks for the clarifications. The revised labels (clean copy and changes tracked versions) are attached.

Ann

---

**From:** Reeves, Craig [mailto:Reeves.Craig@epa.gov]

**Sent:** August 02, 2016 7:27 AM

**To:** Ann Tillman <Ann@PyxisRC.com>

**Subject:** RE: 89966-U: Pyraclostrobin Technical

Ann:

The "by mouth" is a recent reversal from the EPA attorneys, they decided that the wording needed to be put back in to clarify.

The bolded, capitalized "DO NOT", comes from the me-too (7969-185), but I think either capitalized, or bold will be fine.

Thanks – Craig

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**From:** Ann Tillman [mailto:Ann@PyxisRC.com]

**Sent:** Monday, August 01, 2016 3:43 PM

**To:** Reeves, Craig <Reeves.Craig@epa.gov>

**Subject:** RE: 89966-U: Pyraclostrobin Technical

Craig,

I reviewed the label comments you sent. I have a question on the First Aid language under "If Swallowed". You said to add "by mouth" to the sentence under the fourth bullet. I took this language from the label for EPA Reg. No. 7969-185 and from the text listed in Table 9 of the Label Review Manual. Is Table 9 in the Label Review Manual wrong?

Must the bolded phrases "Do Not" in the Environmental Hazards section be capitalized or is making that text bold sufficient?

Ann

*Ann M. Tillman, Ph.D.  
Pyxis Regulatory Consulting, Inc.  
4110 136<sup>th</sup> St. Ct. NW  
Gig Harbor, WA 98332*

Office (253) 853-7369  
Fax (253) 853-5516  
Email [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)

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**From:** Reeves, Craig [<mailto:Reeves.Craig@epa.gov>]  
**Sent:** August 01, 2016 1:24 PM  
**To:** Ann Tillman <[Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical

Ann:

I have reviewed the label and note the following items to be revised:

Page 1: "**CAUTION**" needs to be in font 14, since 'KOOROC' appears to be in font 10.

Also add: "**PRECAUCION**", and Spanish wording below in rectangular box; please see label 7969-185.

"Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand the label, find someone to explain it to you in detail.)"

Page 1: Under FIRST AID; add "by mouth"; sentence should read as follows: "Do not give anything by mouth to an unconscious person." In the same box, bold "**DO NOT**" twice.

Page 1: Under "HOTLINE NUMBER", please see NPIC website: their hours are from Monday – Friday, 8:00am – 12pm, Pacific Standard Time. They are not for medical emergencies but only for general information. We recommend to list another number for medical emergencies.

Page 2: Under "ENVIRONMENTAL HAZARDS", bold "**DO NOT**"; please see label 7969-185. The 7969-185 label has 3 "**DO NOT**" in that section.

In last sentence, change "... his ..." to the following: "... their ..."

If you have any questions please contact me.

Regards – Craig  
703 347-0486

---

**From:** Ann Tillman [<mailto:Ann@PyxisRC.com>]  
**Sent:** Thursday, July 28, 2016 3:46 PM  
**To:** Reeves, Craig <[Reeves.Craig@epa.gov](mailto:Reeves.Craig@epa.gov)>  
**Cc:** Kish, Tony <[Kish.Tony@epa.gov](mailto:Kish.Tony@epa.gov)>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical

Thanks, Craig.

Ann

Ann M. Tillman, Ph.D.  
Pyxis Regulatory Consulting, Inc.

4110 136<sup>th</sup> St. Ct. NW  
Gig Harbor, WA 98332  
Office (253) 853-7369  
Fax (253) 853-5516  
Email [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)

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**From:** Reeves, Craig [<mailto:Reeves.Craig@epa.gov>]  
**Sent:** July 28, 2016 2:50 PM  
**To:** Ann Tillman <[Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)>  
**Cc:** Kish, Tony <[Kish.Tony@epa.gov](mailto:Kish.Tony@epa.gov)>  
**Subject:** 89966-U: Pyraclostrobin Technical

Ann Tillman  
Pyxis Regulatory Consulting, Inc.  
Agent Greenfields Marketing, Ltd  
4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Ms. Tillman:

I am reviewing Greenfields Marketing submittal for the product referenced above and will be back in contact in the near future. If you have any questions let me know.

Sincerely

Craig Reeves  
USEPA/RD/FB  
703 347-0486

## Reeves, Craig

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Must the bolded phrases "Do Not" in the Environmental Hazards section be capitalized or is making that text bold sufficient?

Ann

*Ann M. Tillman, Ph.D.*  
*Pyxis Regulatory Consulting, Inc.*  
*4110 136<sup>th</sup> St. Ct. NW*  
*Gig Harbor, WA 98332*  
*Office (253) 853-7369*  
*Fax (253) 853-5516*  
*Email [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)*

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**Sent:** August 01, 2016 1:24 PM  
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<p>"Si usted no entiende ta etiqueta, busque a alguien para que se la explique a usted en detaile. (If you do not understand the label, find someone to explain it to you in detail.)</p>
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**Page 2:** Under "ENVIRONMENTAL HAZARDS", bold "**DO NOT**"; please see label 7969-185. The 7969-185 label has 3 "**DO NOT**" in that section.

In last sentence, change "... his ..." to the following: "... their ..."

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703 347-0486

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**Sent:** Thursday, July 28, 2016 3:46 PM  
**To:** Reeves, Craig <[Reeves.Craig@epa.gov](mailto:Reeves.Craig@epa.gov)>  
**Cc:** Kish, Tony <[Kish.Tony@epa.gov](mailto:Kish.Tony@epa.gov)>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical

Thanks, Craig.

Ann

*Ann M. Tillman, Ph.D.  
Pyxis Regulatory Consulting, Inc.  
4110 136<sup>th</sup> St. Ct. NW  
Gig Harbor, WA 98332  
Office (253) 853-7369  
Fax (253) 853-5516  
Email [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)*

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**From:** Reeves, Craig [<mailto:Reeves.Craig@epa.gov>]  
**Sent:** July 28, 2016 2:50 PM  
**To:** Ann Tillman <[Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)>  
**Cc:** Kish, Tony <[Kish.Tony@epa.gov](mailto:Kish.Tony@epa.gov)>  
**Subject:** 89966-U: Pyraclostrobin Technical

Ann Tillman  
Pyxis Regulatory Consulting, Inc.  
Agent Greenfields Marketing, Ltd  
4110 136th St. NW  
Gig Harbor, WA 98332

Ms. Tillman:

I am reviewing Greenfields Marketing submittal for the product referenced above and will be back in contact in the near future. If you have any questions let me know.

Sincerely

Craig Reeves  
USEPA/RD/FB  
703 347-0486

## Reeves, Craig

---

**From:** Manupella, Matthew  
**Sent:** Thursday, August 04, 2016 4:08 PM  
**To:** Reeves, Craig  
**Cc:** Kish, Tony  
**Subject:** RE: DCI: Pyraclostrobin (89966-U)  
**Attachments:** GDCI-099100-1467.pyraclostrobin.BASFcorp.pdf

Hi Craig-

The DCI was issued in October of 2015, and the longest study duration is 24 months. We are expecting everything to be completed by October 2017. We waived 850.1400 (freshwater fish ELS with rainbow trout) and 850.3030 (honeybee toxicity of residues on forage). We've received a honeybee chronic tox study, but it hasn't been reviewed.

Let me know if you need any additional information.

Best,  
Matt

---

**From:** Reeves, Craig  
**Sent:** Thursday, August 04, 2016 1:53 PM  
**To:** Manupella, Matthew <Manupella.Matthew@epa.gov>  
**Cc:** Kish, Tony <Kish.Tony@epa.gov>  
**Subject:** DCI: Pyraclostrobin (89966-U)

Matthew:

I am working on the registration of a Pyraclostrobin technical and need information on the outstanding DCI requirement:

- When was it issued
- When are the due dates: 12 months & 24 months?
- Has any DCI information been submitted to date?

I called and left a message.

Thanks Craig  
RD/FB



## Reeves, Craig

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**From:** Ann Tillman <Ann@PyxisRC.com>  
**Sent:** Friday, August 05, 2016 10:34 AM  
**To:** Reeves, Craig  
**Cc:** Kish, Tony  
**Subject:** RE: 89966-U: Pyraclostrobin Technical: conference call

The office number is 253-853-7369.

Ann

---

**From:** Reeves, Craig [mailto:Reeves.Craig@epa.gov]  
**Sent:** August 05, 2016 10:18 AM  
**To:** Ann Tillman <Ann@PyxisRC.com>  
**Cc:** Kish, Tony <Kish.Tony@epa.gov>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical: conference call

Ann:

11:30am EST is good. What is the best number to call you on?

Regards -- Craig

---

**From:** Ann Tillman [mailto:Ann@PyxisRC.com]  
**Sent:** Friday, August 05, 2016 10:01 AM  
**To:** Reeves, Craig <Reeves.Craig@epa.gov>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical: conference call

Craig,

I can be available at 10:30 a.m. EST or 11:30 a.m.

Ann

---

**From:** Reeves, Craig [mailto:Reeves.Craig@epa.gov]  
**Sent:** August 05, 2016 9:39 AM  
**To:** Ann Tillman <Ann@PyxisRC.com>  
**Subject:** 89966-U: Pyraclostrobin Technical: conference call

Ann:

Since a DCI Pyraclostrobin was sent out October 2015 there are some conditions (mostly Data Matrix) to be discussed.

Would you be available for a conference call today? If so please provide me with 2 options for today, the call should take about 20 minutes.

Thanks – Craig

---

**From:** Ann Tillman [mailto:Ann@PyxisRC.com]  
**Sent:** Thursday, August 04, 2016 3:07 PM  
**To:** Reeves, Craig <Reeves.Craig@epa.gov>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical

Craig,  
  
Changes were made. See attachment.  
  
Ann

---

**From:** Reeves, Craig [mailto:Reeves.Craig@epa.gov]  
**Sent:** August 04, 2016 11:25 AM  
**To:** Ann Tillman <Ann@PyxisRC.com>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical

Ann:

Please add the following to 89966-U label, page 3, "STORAGE" section:

"Store in original container in a cool, dry, well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up, and collected and properly disposed." The preceding section is from 7969-185.

Please send me the revised label as soon as possible.

Regards – Craig

---

**From:** Ann Tillman [mailto:Ann@PyxisRC.com]  
**Sent:** Thursday, August 04, 2016 8:29 AM  
**To:** Reeves, Craig <Reeves.Craig@epa.gov>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical

Craig,  
  
I made the changes to indicate NPIC for non-emergency calls and the national poison control center for emergency calls. Let me know if that text is acceptable.  
  
Ann

---

**From:** Reeves, Craig [mailto:Reeves.Craig@epa.gov]  
**Sent:** August 04, 2016 8:14 AM  
**To:** Ann Tillman <Ann@PyxisRC.com>  
**Subject:** 89966-U: Pyraclostrobin Technical

Ann:

When I looked at NPIC (National Pesticides Information Center: 800-858-7378) this morning, I see that they are "open from 8:00am to 12:00pm Pacific (Standard) time Monday – Friday". Please revise your NPIC information on Page 1 of the label. The information at this website is not for emergencies but is informational.

Please send me revised labels as soon as possible.

Thanks – Craig

---

**From:** Ann Tillman [mailto:Ann@PyxisRC.com]

**Sent:** Tuesday, August 02, 2016 8:31 AM

**To:** Reeves, Craig <Reeves.Craig@epa.gov>

**Subject:** RE: 89966-U: Pyraclostrobin Technical

Craig,

Thanks for the clarifications. The revised labels (clean copy and changes tracked versions) are attached.

Ann

---

**From:** Reeves, Craig [mailto:Reeves.Craig@epa.gov]

**Sent:** August 02, 2016 7:27 AM

**To:** Ann Tillman <Ann@PyxisRC.com>

**Subject:** RE: 89966-U: Pyraclostrobin Technical

Ann:

The "by mouth" is a recent reversal from the EPA attorneys, they decided that the wording needed to be put back in to clarify.

The bolded, capitalized "DO NOT", comes from the me-too (7969-185), but I think either capitalized, or bold will be fine.

Thanks – Craig

---

**From:** Ann Tillman [mailto:Ann@PyxisRC.com]

**Sent:** Monday, August 01, 2016 3:43 PM

**To:** Reeves, Craig <Reeves.Craig@epa.gov>

**Subject:** RE: 89966-U: Pyraclostrobin Technical

Craig,

I reviewed the label comments you sent. I have a question on the First Aid language under "If Swallowed". You said to add "by mouth" to the sentence under the fourth bullet. I took this language from the label for EPA Reg. No. 7969-185 and from the text listed in Table 9 of the Label Review Manual. Is Table 9 in the Label Review Manual wrong?

Must the bolded phrases "Do Not" in the Environmental Hazards section be capitalized or is making that text bold sufficient?

Ann

*Ann M. Tillman, Ph.D.*

*Pyxis Regulatory Consulting, Inc.*

*4110 136<sup>th</sup> St. Ct. NW*

*Gig Harbor, WA 98332*

Office (253) 853-7369  
Fax (253) 853-5516  
Email [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)

---

**From:** Reeves, Craig [<mailto:Reeves.Craig@epa.gov>]  
**Sent:** August 01, 2016 1:24 PM  
**To:** Ann Tillman <[Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical

Ann:

I have reviewed the label and note the following items to be revised:

Page 1: **“CAUTION”** needs to be in font 14, since ‘KOOROC’ appears to be in font 10.

Also add: **“PRECAUCION”**, and Spanish wording below in rectangular box; please see label 7969-185.

“Si usted no entiende ta etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand the label, find someone to explain it to you in detail.)

Page 1: Under FIRST AID; add “by mouth”; sentence should read as follows: “Do not give anything by mouth to an unconscious person.” In the same box, bold **“DO NOT”** twice.

Page 1: Under “HOTLINE NUMBER”, please see NPIC website: their hours are from Monday – Friday, 8:00am – 12pm, Pacific Standard Time. They are not for medical emergencies but only for general information. We recommend to list another number for medical emergencies.

Page 2: Under “ENVIRONMENTAL HAZARDS”, bold **“DO NOT”**; please see label 7969-185. The 7969-185 label has 3 **“DO NOT”** in that section.

In last sentence, change “... his ... “ to the following: “... their ...”

If you have any questions please contact me.

Regards – Craig  
703 347-0486

---

**From:** Ann Tillman [<mailto:Ann@PyxisRC.com>]  
**Sent:** Thursday, July 28, 2016 3:46 PM  
**To:** Reeves, Craig <[Reeves.Craig@epa.gov](mailto:Reeves.Craig@epa.gov)>  
**Cc:** Kish, Tony <[Kish.Tony@epa.gov](mailto:Kish.Tony@epa.gov)>  
**Subject:** RE: 89966-U: Pyraclostrobin Technical

Thanks, Craig.

Ann

Ann M. Tillman, Ph.D.  
Pyxis Regulatory Consulting, Inc.

4110 136<sup>th</sup> St. Ct. NW  
Gig Harbor, WA 98332  
Office (253) 853-7369  
Fax (253) 853-5516  
Email [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)

---

**From:** Reeves, Craig [<mailto:Reeves.Craig@epa.gov>]

**Sent:** July 28, 2016 2:50 PM

**To:** Ann Tillman <[Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)>

**Cc:** Kish, Tony <[Kish.Tony@epa.gov](mailto:Kish.Tony@epa.gov)>

**Subject:** 89966-U: Pyraclostrobin Technical

Ann Tillman  
Pyxis Regulatory Consulting, Inc.  
Agent Greenfields Marketing, Ltd  
4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Ms. Tillman:

I am reviewing Greenfields Marketing submittal for the product referenced above and will be back in contact in the near future. If you have any questions let me know.

Sincerely

Craig Reeves  
USEPA/RD/FB  
703 347-0486



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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 Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Greenfields Marketing, Ltd. c/o Pyxis Regulatory 4110 136th St. NW Gig Harbor, WA 253-853-7369	EPA Registration Number/File Symbol 89966-U
Active Ingredient(s) and/or representative test compound(s) Pyraclostrobin	Date Aug. 5, 2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) TGAI	Product Name Pyraclostrobin Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Digitally signed by Ann M. Tillman  
 DN: cn=Ann M. Tillman, o=Pyxis  
 Regulatory Consulting, Inc., ou=Pyxis,  
 email=AnnePyxisRC.com, c=US  
 Date: 2016.08.05 11:59:11 -04'00'

Date

Aug. 5, 2016

Typed or Printed Name and Title

Ann M. Tillman, Agent



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## DATA MATRIX

Date: Aug. 5, 2016

EPA Reg. No./ File Symbol: 89966-U

Page 1 of 6

Applicant's/Registrant's Name and Address:

Greenfields Marketing, Ltd.  
P.O. Box 115887, Dubai  
United Arab Emirates

Product:

Pyraclostrobin Technical

Ingredient: Pyraclostrobin (CAS No. 175013-18-0)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Product Specific Data Requirements</b>					
830.1550 ✓	Product Identity and Composition	49750301 ✓	Greenfields Marketing, Ltd.	OWN	
830.1600 ✓	Description of Materials Used to Produce the Product	49750301 ✓	Greenfields Marketing, Ltd.	OWN	
830.1620 ✓	Description of Production Process	49750301 ✓	Greenfields Marketing, Ltd.	OWN	
830.1650 ✓	Description of Formulation Process				Not Required <sup>1</sup>
830.1670 ✓	Discussion of Formation of Impurities	49750301 ✓	Greenfields Marketing, Ltd.	OWN	
830.1700 ✓	Preliminary Analysis	49750302 ✓	Greenfields Marketing, Ltd.	OWN	
		49750303 ✓	Greenfields Marketing, Ltd.	OWN	
		49750304 ✓	Greenfields Marketing, Ltd.	OWN	
830.1750 ✓	Certified Limits	49750301 ✓	Greenfields Marketing, Ltd.	OWN	
830.1800 ✓	Enforcement Analytical Method	49750302 ✓	Greenfields Marketing, Ltd.	OWN	
		49750303 ✓	Greenfields Marketing, Ltd.	OWN	
830.6302	Color	49750305 ✓	Greenfields Marketing, Ltd.	OWN	
830.6303	Physical State	49750305 ✓	Greenfields Marketing, Ltd.	OWN	
830.6304	Odor	49750305 ✓	Greenfields Marketing, Ltd.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	49750306 ✓	Greenfields Marketing, Ltd.	OWN	Data
		49750307 ✓	Greenfields Marketing, Ltd.	OWN	Waiver <sup>2</sup>

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Aug. 5, 2016



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## DATA MATRIX

Date: Aug. 5, 2016	EPA Reg. No./ File Symbol: 89966-U	Page 2 of 6
Applicant's/Registrant's Name and Address: Greenfields Marketing, Ltd. P.O. Box 115887, Dubai United Arab Emirates	Product: Pyraclostrobin Technical	
Ingredient: Pyraclostrobin (CAS No. 175013-18-0)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6314	Oxidation/Reduction: Chemical Incompatibility	49750305	Greenfields Marketing, Ltd.	OWN	
830.6315	Flammability	49750306	Greenfields Marketing, Ltd.	OWN	Waiver <sup>3</sup>
830.6316	Explosibility	49750306	Greenfields Marketing, Ltd.	OWN	Waiver <sup>4</sup>
830.6317	Storage Stability	49750305	Greenfields Marketing, Ltd.	OWN	
830.6319	Miscibility				Not Required <sup>5</sup>
830.6320	Corrosion Characteristics	49750305	Greenfields Marketing, Ltd.	OWN	
830.6321	Dielectric Breakdown Voltage				Not Required <sup>5</sup>
830.7000	pH	49750305	Greenfields Marketing, Ltd.	OWN	
830.7050	UV/Visible Absorption	49750305	Greenfields Marketing, Ltd.	OWN	
830.7100	Viscosity	49750306	Greenfields Marketing, Ltd.	OWN	Not Required <sup>5</sup>
830.7200	Melting Point/Melting Range	49750305	Greenfields Marketing, Ltd.	OWN	
830.7220	Boiling Point/Boiling Range				Not Required
830.7300	Density/Relative Density/Bulk Density	49750305	Greenfields Marketing, Ltd.	OWN	
830.7370	Dissociation Constants in Water	49750306	Greenfields Marketing, Ltd.	OWN	Waiver <sup>7</sup>
830.7520	Particle Size, Fiber Length, and Diameter Distribution				Not Required <sup>5</sup>
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	49750306	Greenfields Marketing, Ltd.	PL	

Signature 	Name and Title Ann M. Tillman, Consultant	Date Aug. 5, 2016
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## DATA MATRIX

Date: Aug. 5, 2016

EPA Reg. No./ File Symbol: 89966-U

Page 3 of 6

Applicant's/Registrant's Name and Address:

Greenfields Marketing, Ltd.  
P.O. Box 115887, Dubai  
United Arab Emirates

Product:

Pyraclostrobin Technical

Ingredient: Pyraclostrobin (CAS No. 175013-18-0)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	49750306	Greenfields Marketing, Ltd.	PL	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	49750306	Greenfields Marketing, Ltd.	PL	
870.1100	Acute Oral Toxicity: Rat	Cite-All		PAY	
870.1200	Acute Dermal Toxicity: Rat	Cite-All		PAY	
870.1300	Acute Inhalation Toxicity: Rat	Cite-All		PAY	
870.2400	Primary Eye Irritation: Rabbit	Cite-All		PAY	
870.2500	Primary Dermal Irritation	Cite-All		PAY	
870.2600	Dermal Sensitization	Cite-All		PAY	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Aug. 5, 2016



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## DATA MATRIX

Date: Aug. 5, 2016

EPA Reg. No./ File Symbol: 89966-U

Page 4 of 6

Applicant's/Registrant's Name and Address:

Greenfields Marketing, Ltd.  
P.O. Box 115887, Dubai  
United Arab Emirates

Product:

Pyraclostrobin Technical

Ingredient: Pyraclostrobin (CAS No. 175013-18-0)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Pyraclostrobin Product Specific and Generic Data Requirements, including studies listed in the Oct. 20, 2015 GDCI-099100-1467. ✓</b>					
Greenfields Marketing, Ltd. has sent offers-to-pay letters to the following companies on the pyraclostrobin data submitters list of June 30, 2015.					
		Cite-All	Bonide Products, Inc.	PAY	
		Cite-All	Bayer CropScience LP	PAY	
		Cite-All	FMC Corp.	PAY	
		Cite-All	BASF Corp.	PAY	
		Cite-All	BASF Corp.	PAY	
		Cite-All	BASF Corp.	PAY	
		Cite-All	Tessenderlo Kerley, Inc.	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	Kureha Corp.	PAY	
		Cite-All	FIFRA Endangered Species Task Force LLC	PAY	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Aug. 5, 2016



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## DATA MATRIX

Date: Aug. 5, 2016

EPA Reg. No./ File Symbol: 89966-U

Page 5 of 6

Applicant's/Registrant's Name and Address:

Greenfields Marketing, Ltd.  
P.O. Box 115887, Dubai  
United Arab Emirates

Product:

Pyraclostrobin Technical

Ingredient: Pyraclostrobin (CAS No. 175013-18-0)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Agricultural Handlers Exposure Task Force	PAY	
		Cite-All	Willowood, LLC	PAY	
		Cite-All	Liberty Crop Protection LLC	PAY	

Signature

Name and Title

Ann M. Tillman, Consultant

Date

Aug. 5, 2016

## Endnotes for Data Matrix for Pyraclostrobin Technical

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- <sup>1</sup> **830.1650** - These data are not required for the registration of a technical grade active ingredient product. See 830.1620 for production process information.
- <sup>2</sup> **830.6313** - Greenfields Marketing, Ltd. will not package Pyraclostrobin Technical in metal containers, and Pyraclostrobin Technical is not expected to come into contact with metals or metal ions during its storage or use. Therefore, a waiver from the requirement of these data is requested. Pyraclostrobin Technical was found to be stable at normal and elevated temperatures (Volume 4 of this submission).
- <sup>3</sup> **830.6315** - Greenfields Marketing, Ltd. requests a waiver from the requirement of this data requirement since Pyraclostrobin Technical is a solid and does not contain flammable materials. Please refer to the Confidential Statement of Formula for Pyraclostrobin Technical.
- <sup>4</sup> **830.6316** - Greenfields Marketing, Ltd. requests a waiver from this data requirement because pyraclostrobin does not have the chemical bonds or functional groups associated with explosive chemicals.
- <sup>5</sup> **830.6319, 830.6321, 830.7100, 830.7520** - Pyraclostrobin Technical is a solid and not an emulsifiable concentrate and is not to be diluted with petroleum solvents. Therefore, miscibility data are not required for this technical. Pyraclostrobin Technical is not an end use product to be used around electrical equipment, therefore data for dielectric breakdown constant are not required. Pyraclostrobin Technical is a solid and not a liquid, therefore, viscosity data are not required for this product. Greenfields Marketing, Ltd. is seeking a waiver for particle size, fiber length and diameter distribution because Pyraclostrobin Technical is not water insoluble nor is it a fibrous material.
- <sup>6</sup> **830.7220** - This data requirement is not applicable to Pyraclostrobin Technical because it is a solid.
- <sup>7</sup> **830.7370** - Greenfields Marketing, Ltd. is seeking a waiver for this data requirement for Pyraclostrobin Technical because the product does not have any functional groups that would dissociate.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

FEE

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

BARCODE: D 430157; *DECISION NO.: 510433; PC CODE: 099100; PRIA CODE: R333*  
EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing

DATE: July 22, 2016

FROM: Akiva Abramovitch, Ph.D.  
CITAB / RD (7505P)

THROUGH: Shyam B. Mathur, Ph.D.  
Product Chemistry Team Leader  
CITAB / RD (7505P)

TO: Shaunta Hill / Tony Kish, Product Manager, RM 22  
CITAB / RD (7505P)

SUBJECT: Product Chemistry Review of Pyraclostrobin Technical

USE: Technical

MRID NUMBERS: 497503-01 through -06

INTRODUCTION:

The registrant is seeking the registration of a new Pyraclostrobin Technical. This product will be produced in two sites in [REDACTED]. The active ingredient in this product is at a label nominal concentration of 99.0 a.i label claim. In support of this petition, the registrant has submitted a draft label and product chemistry data contained in MRID# 497503-01 through -06 and a basic CSF and alternate CSF both dated October 9, 2015. The basic CSF site is [REDACTED] and the alternate site is [REDACTED]. Both sites use identical manufacturing process and ingredients but one of the ingredients for step 1 is manufactured at the basic site but purchased by the alternate site.

SUMMARY OF FINDINGS:

Table 1. Manufacturing and Impurity Data				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	497503-01	A	
830.1600	Description of materials used to produce the product	497503-01	A	
830.1620	Description of production process	497503-01	A	
830.1670	Discussion of formation of impurities	497503-01	A	
830.1700	Preliminary analysis	497503-02 497503-04	A	The NC of AI (99.0%) is supported by an analysis of 5 batches. Analysis agrees with the label claim NC.
830.1750	Certified limits	497503-01	A	
830.1800	Enforcement analytical method	497503-03	A	Validated HPLC

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required)

\* Product ingredient source information may be entitled to confidential treatment\*

**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRIA CODE: R333**

**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**  
**830 Series Subgroup B (Physical-Chemical Properties)**

Table 2: Physical and Chemical Properties

GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	497503-05	A	Off white
830.6303	Physical state	497503-05	A	Powder-solid
830.6304	Odor	497503-05	A	Mild sweet odor
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	497503-05	A	Stable at 54 C for 14 days
830.6314	Oxidation/reduction: chemical incompatibility	497503-05	A	TGA was found to be non-reactive towards iron powder, water, NH4I-12P04, KMnO4 and kerosene.
830.6315	Flammability	497503-06	A	Product is not flammable.
830.6316	Explosibility	497503-06	A	Product does not contain explosive components
830.6317	Storage stability	497503-05	A	Stable in the commercial packaging for 2 weeks at 54 C
830.6319	Miscibility		W	Product is not an EC nor mixed with petroleum solvents
830.6320	Corrosion characteristics	497503-05	A	Stable in the commercial packaging for 2 weeks at 24 C and no corrosion observed
830.7000	pH	497503-05	A	5.96
830.7050	UV/Visible absorption	497503-05	A	See UV data
830.7100	Viscosity		W	Solid, / waiver
830.7200	Melting point	497503-05	A	59-62 C
830.7220	Boiling point		NA	Solid, waiver
830.7300	Density	497503-05	A	1.477 gm/ml @ 24 °C (92.2 lb/cubic ft)
830.7370	Dissociation constants in water		W	No dissociation
830.7550	Partition coefficient	497503-06 cited	A	Log P o/w= 3.99
830.7840	Water solubility:	497503-06 cited	A	1.9 mg/L at pH 7 at 20 C
830.7950	Vapor pressure	497503-06 cited	A	$2.6 \times 10^{-5}$ mPa

Y = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = in progress or need upgrade; U = Up-grade (additional information required)

See UV data attached following page

**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRIA CODE: R333**  
**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**

Conditions	Neutral Solution	Acidic Solution	Basic Solution
<b>Peak One</b>			
Concentration	$2.786 \times 10^{-5}$ M	$2.786 \times 10^{-5}$ M	$2.786 \times 10^{-5}$ M
Peak Wavelengths	203.41 nm	202.04 nm	216.59 nm
Absorbance Maximum	0.8771 AU	0.9178 AU	0.4513 AU
Molar Absorptivity	31,000	33,000	16,000
Bandwidth	26 nm	27 nm	12 nm
<b>Peak Two</b>			
Concentration	$2.786 \times 10^{-5}$ M	$2.786 \times 10^{-5}$ M	$2.786 \times 10^{-5}$ M
Peak Wavelengths	275.87 nm	275.09 nm	275.11 nm
Absorbance Maximum	0.6942 AU	0.6838 AU	0.6716 AU
Molar Absorptivity	25,000	25,000	24,000
Bandwidth	35 nm	34 nm	34 nm

Solution	Neutral (pH 6.54)	Acidic (pH 1.40)	Alkaline (pH 12.58)
Final Volume (mL)	10		
Concentration (mol/L)	3.219	3.219	2.253
Wavelength of Maximum (nm)	No peak found	194.0	255.9
Absorbance Observed (at nm)	N/A	0.162	0.361
$\epsilon$ Value calculated	N/A	50326.2	16023.1
Band width calculated (nm)	N/A	4.4	56.7

**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRIA CODE: R333**  
**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**

**CONCLUSIONS:**

CITAB has reviewed this submission and reports the following findings:

1. This submission satisfies the data requirements as specified in 40 CFR 158.320, 158.325, 158.330, 158.340, 158.345, 158.350, and 158.355 with respect to product identity and composition, description of materials used to produce the product, description of production process, discussion of formation of impurities, preliminary analysis, certified limits, and enforcement analytical method.
2. The five batch analysis supports the composition shown on the CSFs for the basic and alternate sites and the label claim of 99.0%. The mean purity of Pyraclostrobin Technical NC was measured at 99.0% w/w with a range from 98.7% to 99.5% w/w in the two sites.
3. The registrant declared identified impurities to be below the level of toxicological concern. Levels of solvents and ingredients of toxicological concern were listed on the CSFs.
4. The product chemistry data requirements have been satisfied including the Storage Stability and Corrosion Characteristics (830.6313, 6317) data. ✓
5. The basic CSF [REDACTED] and alternate CSF [REDACTED] both dated October 9, 2015 for the two sites in [REDACTED] are acceptable. ✓
6. This product is substantially similar to the cited product EPA Reg. No. 7969-185. ✓

\*Product ingredient source information may be entitled to confidential treatment\*

\*Manufacturing process information may be entitled to confidential treatment\*



**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRIA CODE: R333**  
**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**  
**CONFIDENTIAL APPENDIX:**

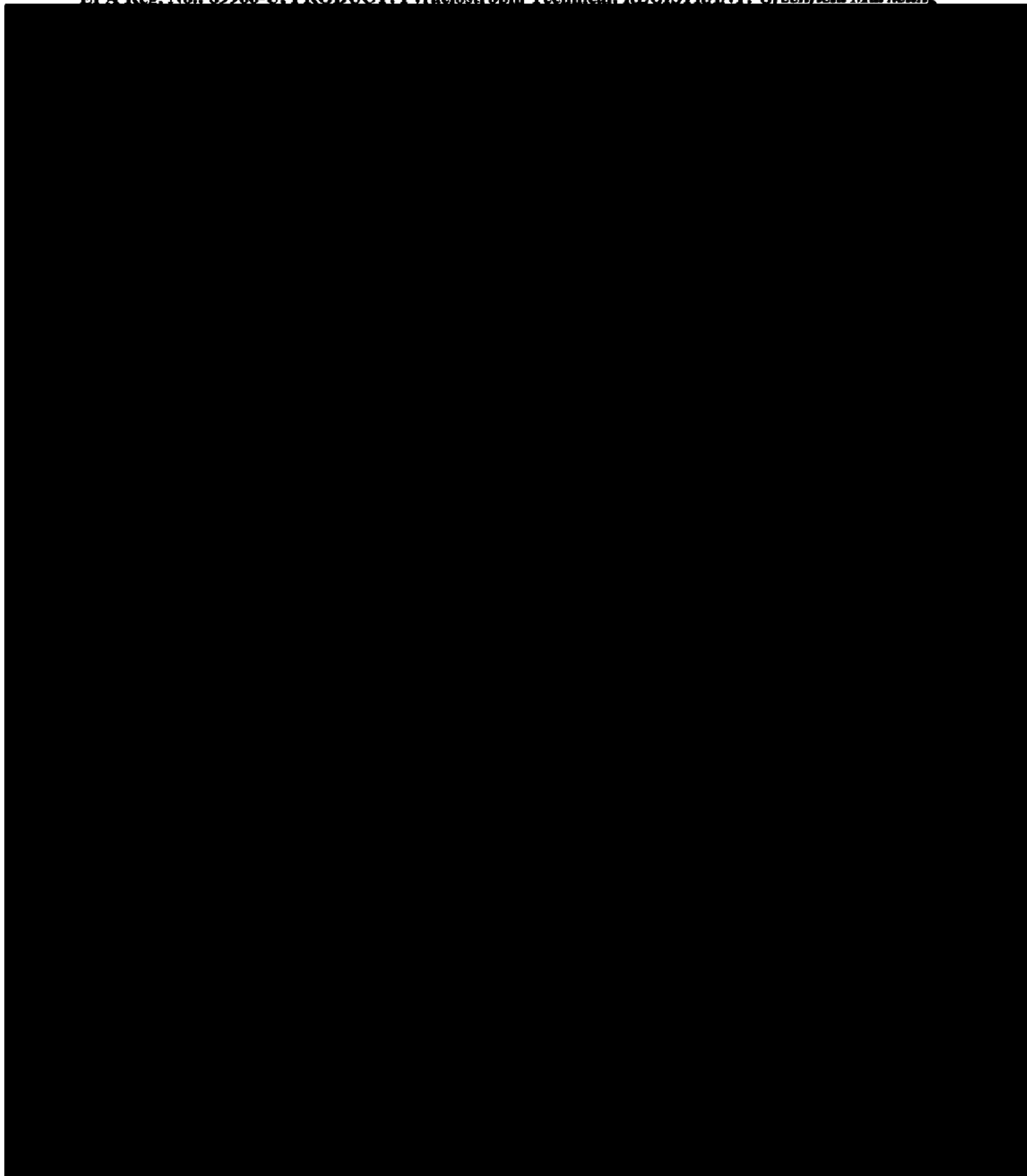
\*Manufacturing process information may be entitled to confidential treatment\*

**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRIA CODE: R333**  
**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**

\*Manufacturing process information may be entitled to confidential treatment\*

**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRLA CODE: R333**

**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**



\*Manufacturing process information may be entitled to confidential treatment\*

**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRLA CODE: R333**  
**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**

\*Manufacturing process information may be entitled to confidential treatment\*

**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRLA CODE: R333**  
**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**

\*Manufacturing process information may be entitled to confidential treatment\*

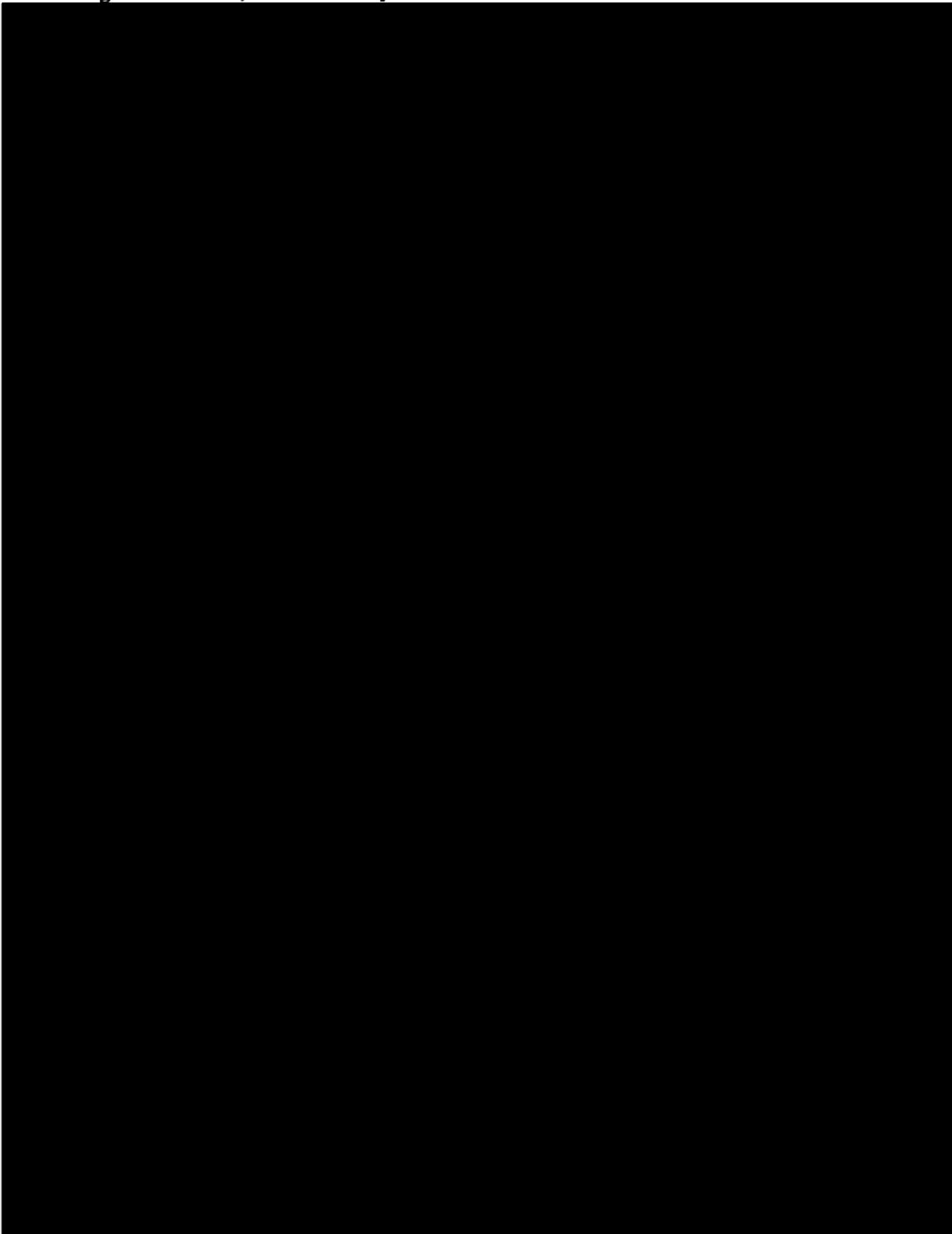
**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRLA CODE: R333**

**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**

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**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**

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**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRLA CODE: R333**

**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**

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**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRLA CODE: R333**  
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**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRLA CODE: R333**  
**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**

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**BARCODE: D 430157; DECISION NO.: 510433; PC CODE: 099100; PRLA CODE: R333**  
**EPA Reg. No.: 89966-U; PRODUCT: Pyraclostrobin Technical; REGISTRANT: Greenfield Marketing**

\*Manufacturing process information may be entitled to confidential treatment\*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION

10/NOV/2015

SIMILARITY MEMORANDUM

Subject: Name of Pesticide Product: Pyraclostrobin Technical  
EPA Reg. No. /File Symbol: 89966-U  
DP Barcode: D430004  
Decision No: 510433  
Action Code: ~~R301~~ **R333**  
PC Code: 099100 (pyraclostrobin)

From: Eugenia McAndrew, Biologist *Eugenia McAndrew*

Through: John C. Redden, M.S., Senior Risk Assessor  
Chemistry, Inerts and Toxicology Assessment Branch *JCR*  
Registration Division (7505P)

To: Tony Kish, Risk Manager 22  
Fungicide Branch  
Registration Division (7505P)

Applicant: Greenfields Marketing, LLC  
c/o Pyxis Regulatory Consulting, Inc.  
4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Pyraclostrobin	99.0
<u>Other Ingredients:</u>	<u>1.0</u>
Total:	100.0%

**ACTION REQUESTED:** Similarity determination for 89966-U, proposed product, and 07969-185, cited product.

**BACKGROUND:** Greenfields Marketing, LLC has applied for registration of Pyraclostrobin Technical, EPA File Symbol 89966-U, claiming to be substantially similar to Pyraclostrobin Technical, EPA Reg. No. 7969-185. Both products are technical grade for formulating only. The submission includes a basic CSF dated October 9, 2015, label, data matrix and company letter.

The registrant is using the cite all method of data support to satisfy the acute toxicity data requirements. A search of the OPP electronic databases shows that the Technical Review Branch in the Registration Division assigned an acute toxicity profile to the cited product, 7969-185, in a 2001 memo (Redden; D275781; EPA File Symbol 7969-RIL; 24/JULY/2001). The Toxicity Category for acute inhalation was originally Category II but was changed to Category III in a later memo based on additional information sent in by the registrant (Hashim; D339352; EPA File Symbol 7969-ELI; 27/SEP/2007).

#### RECOMMENDATIONS:

1. We compared the basic CSFs of the proposed product, 89966-U, and the cited product, 07969-185, and determined that the two products are substantially similar.
2. The acute toxicity profile for the proposed product, Pyraclostrobin Technical, EPA File Symbol 89966-U, is as follows:

acute oral toxicity	IV	cited	EPA Reg. No. 7969-185
acute dermal toxicity	III	cited	EPA Reg. No. 7969-185
acute inhalation toxicity	III	cited	EPA Reg. No. 7969-185
primary eye irritation	III	cited	EPA Reg. No. 7969-185
primary skin irritation	III	cited	EPA Reg. No. 7969-185
dermal sensitization	negative	cited	EPA Reg. No. 7969-185

3. The proposed basic CSF submitted for 89966-U must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

**LABELING:** Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

**PRODUCT ID #:** 089966-00004  
**PRODUCT NAME:** Pyraclostrobin Technical

#### PRECAUTIONARY STATEMENTS

**SIGNAL WORD:** CAUTION

**Hazards to Humans and Domestic Animals:**

Harmful if absorbed through skin. Harmful if inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**First Aid:**

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

**DP BARCODE No.:** D430157; **FILE SYMBOL No.:** 89966-U (basic & alt CSF #1 screen); **PRODUCT NAME:** Pyroclostin Technical; **DECISION No.:** 510433; **PC Code(s):** 099100; **ACTION CODE:** R333; **FOOD Use:** Yes

**DATE OUT:** December 4, 2015

**SUBJECT:** 45/90 screen results for technical product "Pyroclostin Technical"

**FROM:** Shyam Mathur,  
Product Chemistry Team Leader  
CITAB / RD (7505P)

**TO:** Shaunta Hill / Tony Kish, RM 22  
Fungicide Branch / RD (7505P)

**Company Name:** Greenfields marketing Ltd.  
**Active Ingredient(s):** Pyroclostin (99.0%)  
**MRID Nos:** 49750301 to 49750306

**CONCLUSION:**

**Deficiencies:** No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

**Group A:** All required data submitted.

Note to reviewer: 830.1620 (production process) – Technical is produced at two sites, both sites use the manufacturing process, except slight difference in Step 1. [REDACTED]

**Group B:** All required data submitted, cited or waiver request.

**CSF:** Proposed basic & alt CSF # 1 (both dated 10-09-2015) submitted  
Basic CSF Produced at – [REDACTED]

**Product label:** Submitted

Note to PM: The proposed product was found to be incompatible with oxidizing agent. The registrant is recommended to add the following statement under Physical-Chemical Hazards on the product label:

"Do not mix or allow coming in contact with oxidizing agent. Hazardous Chemical reaction may occur"

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to author of this report the corrected deficiencies in response to 10 day letter. The corrected information will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

\*Product ingredient source information may be entitled to confidential treatment\*

## Memorandum

Date: 11/2/15

To: PM 22, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

November 02, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

WAGNER REGULATORY ASSOCIATES, INC  
GREENFIELDS MARKETING LTD.  
PO.BOX : 640  
HOCKESSIN, DE 19707

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 22-OCT-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Material Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

October 23, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-510433  
EPA File Symbol or Registration Number: 89966-U  
Product Name: PYRACLOSTROBIN TECHNICAL  
EPA Receipt Date: 22-Oct-2015  
EPA Company Number: 89966  
Company Name: GREENFIELDS MARKETING LTD.

ANN TILLMAN  
AGENT FOR: GREENFIELDS MARKETING LTD.  
PYXIS REGULATORY CONSULTING INC.  
4110 136TH ST., NW  
GIG HARBOR, WA 98332

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R333

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE INGREDIENT;REQUIRES SCIENCE DATA REVIEW;NEW PHYSICAL FORM;CITE-ALL OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in cursive script, appearing to read "Teresa Downs", is written over the typed name.

Front End Processing Staff

Information Technology & Resources Management Division

**Fee for Service**

*K*  
{976007'~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies?      ☐ Fee Waiver?

☐ volpay    % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 22

Receipt No.

S- 976007

EPA File Symbol/Reg. No.

89966-U

Pin-Punch Date:

10/22/2015

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R333

Granted: R333

Amount Due: \$ 19,838

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Shanta Adee

Date: 10/23/15

Remarks:

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 10-22-15

Experts In-Processing Signature: B.B. Date 10-26-15 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>89966-U</u>		EPA Receipt Date: <u>10-22-15</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<u>No inerts to review</u>					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

**Comments:**

Documentation: (PASS)

- All required forms are complete.

Inerts: (N/A)

- Technical and impurities only, no inerts to review.

11-3: (PASS)

- MRID 497503

Status: (PASS)

- MS 11/02/15

## Nicki Purnell

---

**From:** notification@pay.gov  
**Sent:** Tuesday, October 20, 2015 5:25 AM  
**To:** Nicki Purnell  
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or [yanchulis.michael@epa.gov](mailto:yanchulis.michael@epa.gov).

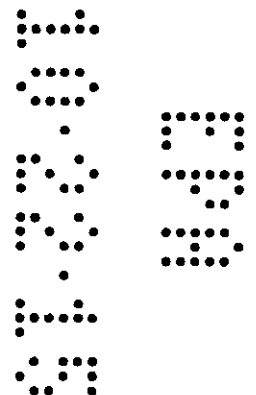
Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 2500J817  
Agency Tracking ID: 74894130035  
Transaction Type: Sale  
Transaction Date: 10/20/2015 08:24:42 AM EDT

Account Holder Name: Brian Heinze

Transaction Amount: \$19,838.00  
Billing Address: 1600 NW Garden Valley Blvd  
Billing Address 2: Suite 12  
City: Roseburg  
State/Province: OR  
Zip/Postal Code: 97471  
Country: USA  
Card Type: MasterCard  
Card Number: \*\*\*\*\*3276

Registration Number:  
Company Name: Greenfields Marketing Ltd  
Company Number: 89966  
Action Code: R333

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.





**PYXIS REGULATORY CONSULTING, INC.**

4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Phone: 253-853-7369  
Fax: 253-853-5516  
[www.PyxisRC.com](http://www.PyxisRC.com)

49750300

October 20, 2015

**OVERNIGHT DELIVERY**

Tony Kish (Acting PM 22)  
Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

RE: Greenfields Marketing, Ltd.  
Pyraclostrobin Technical (EPA File Symbol 89966- )  
Application for New Pesticide Registration  
PRIA Category R333

Dear Mr. Kish,

On behalf of Greenfields Marketing, Ltd., we are submitting an application for registration of Pyraclostrobin Technical, a technical containing the active ingredient pyraclostrobin. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4) for Basic and Alternate #1 formulations
3. Three (3) copies of the proposed label
4. Certification with Respect to Label Integrity
5. A CD containing a copy of the label
6. Certification with Respect to Citation of Data (EPA Form 8570-34)
7. Agency Internal Use Copy of the Data Matrix (EPA Form 8570-35)
8. Public File Copy of the Data Matrix (EPA Form 8570-35)
9. Copy of PRIA payment
10. Letter of Authorization
11. Product Specific Data

Volume	Guideline No.	Study Title
Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800	Pyraclostrobin Technical: Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits and Enforcement Analytical Method. <b><i>Contains Confidential Business Information.</i></b>
Volume 2	830.1700, 830.1800	Skopec, J. Preliminary Analyses of Five Representative Production Batches of Pyraclostrobin Technical Grade Active Ingredient (TGAI) to Determine Percent Pyraclostrobin and to Quantify its Associated Impurities. <b><i>Contains Confidential Business Information.</i></b>

✓49750301

✓49750302

Data presented in Volume 2 support the Basic CSF and data in Volumes 3 and 4 support the Alternate #1 CSF.

Greenfields Marketing, Ltd. is using the cite-all method of support. As per EPA's interpretations of 40 CFR Parts 152.86(b)(2)(i) and 152.93(b)(2)(i), Greenfield Marketing, Ltd. submitted notices of intent to apply and offers to pay to all companies on the September 30, 2015 Data Submitter's List. This action falls under PRIA category R333 (52: New manufacturing use product; unregistered source of active ingredient). The fee for this action which has been paid is \$19,838.

We trust you will find this application complete. However, please feel free to contact me ((253) 853-7369, [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)) if you have any questions or need any additional information.

Sincerely,

Ann M. Teller

Ann M. Tillman

**Enclosures**

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32  
 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62  
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United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 89966	2. EPA Product Manager T. Kish	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Greenfields Marketing, Ltd./Pyriaclostrobin Technical	PM# 22	
5. Name and Address of Applicant (Include ZIP Code) Greenfields Marketing, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 7969-185 - 98% Product Name Pyriaclostrobin Technical	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under Category R333 (52: New manufacturing use product; unregistered source of active ingredient). The fee which has been paid is \$19,838.00.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) PE lined fiberboard drum	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 55.12 lbs (25 kg)	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product			
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled <input type="checkbox"/> Other					

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Pyxis Regulatory Consulting, Inc.	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped)
2. Signature 	3. Title Consultant	
4. Typed Name Ann M. Tillman	5. Date Oct. 20, 2015	

Digitally signed by Ann M. Tillman  
DN: cn=Ann M. Tillman, o=Pyxis  
Regulatory Consulting, Inc.,  
ou=Pyxis,  
email=Ann@PyxisRC.com, c=US  
Date: 2015.10.19 07:52:14 -0400

# Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

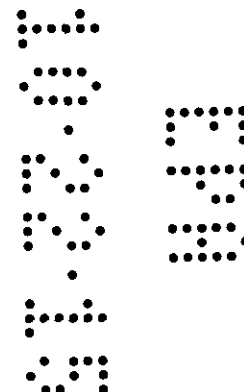
PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
089966-xxxxx	Oct. 20, 2015	089966-xxxxx.20151020.Pyraclostrobin Technical label.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature  
Ann M. Tillman  
Consultant, Greenfields Marketing, Ltd.

Oct. 20, 2015  
Date



# Greenfields Marketing LTD

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October 20, 2015

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

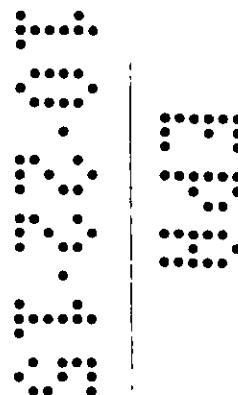
Please let this letter serve to confirm that Janelle Kay, Mike Kellogg, Ann Tillman, Leanne Pruett, Maryanne Geisbush, Nicole O'Loughlin, and Nicki Purnell of Pyxis Regulatory Consulting, Inc. are authorized to act as agent for Greenfields Marketing, Ltd. (EPA Company Number 89966), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our Pyraclostrobin Technical (EPA File Symbol 89966- ) pesticide registrations and applications for registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

  
Akhilesh Bagri  
Director  
Greenfields Marketing, Ltd.

cc: Pyxis Regulatory Consulting, Inc.



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P.O. Box 115887, Dubai, United Arab Emirates.  
Tel: + 971 50 6533 462; Fax: + 971 (4) 332 5688  
e-mail: info@paargroup.com

